REMARKS

The present Office Action addresses and rejects claims 1-21.

Amendments to the Claims

Applicants cancel claims 1, 2, 4, and 21. Claim 3 is amended to replace the term "spiral" with "coil-shaped region," thereby providing proper antecedent basis. Claims 5-6, 8-14, and 18 are amended to depend from claim 3, rather than cancelled claim 1. Claims 11 and 13 are also amended to correspond to claim 3, and in particular to recite that the plurality of fluid entry ports are *formed on an internal portion of the coil-shaped region*, as required by claim 3. No new matter is added.

Rejection Pursuant to 35 U.S.C. §103

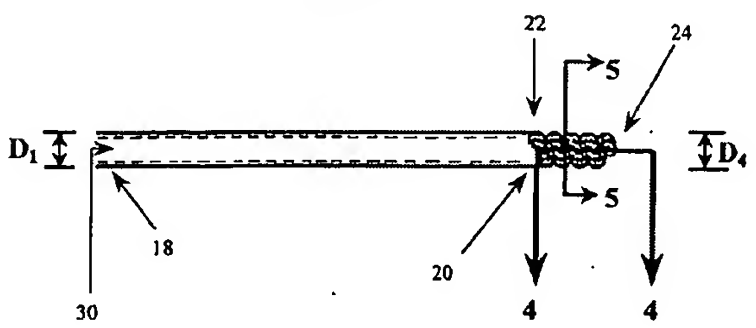
Claims 1, 8-10, and 14-19 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,141,502 of Macaluso, Jr. (Macaluso). Applicants cancel independent claim 1, thereby obviating the basis for this rejection.

The Examiner also rejects claims 2-7, 11-13, 20, and 21 pursuant to 35 U.S.C. §103(a) as being obvious over Macaluso in view of U.S. Patent No. 6,595,966 of Davey et al. (Davey) and U.S. Patent No. 4,950,232 of Ruzicka et al. (Ruzicka). Applicants respectfully disagree.

Independent Claim 3

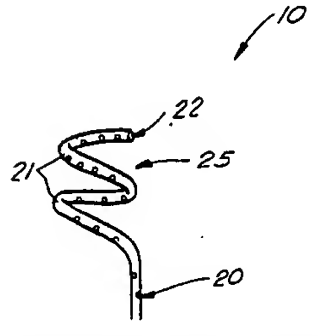
Independent claim 3 requires an implantable fluid management device having a catheter with a coil-shaped region formed in the distal portion and having an outer diameter, measured across the coil, that is substantially equal to an outer diameter of the proximal portion of the catheter. This is illustrated in Figure 3A of the present application, which is reproduced herein for the Examiner's convenience. As shown, D_4 refers to the diameter

Figure 3A



of the coil-shaped region, which is substantially equal to D_1, which is the diameter of the proximal portion of the catheter. Such a configuration is particularly effective for use in treating hydrocephalus, where the diameter of the catheter must remain relatively small "to minimize the damage that may result during implantation of the fluid management device." (Pending Application, page 8, lines 17-18.) The prior art references do not teach or even suggest the claimed fluid management device.

As shown in Figure 7 of Macaluso, a portion of which is reproduced herein, Macaluso discloses a catheter having a helix (21) with an outer diameter that is significantly greater than an outer diameter of the catheter. The Examiner thus relies on Ruzicka as disclosing a catheter with a spiraled tip having a diameter that is substantially equal to the diameter of the catheter itself, arguing that it would have been obvious to modify the catheter of Macaluso to include the dimensions of the spiral tip as disclosed by Ruzicka. Applicants disagree.



At the outset, the Examiner's interpretation of Ruzicka is incorrect. As shown in Figure 7 of Ruzicka, which is reproduced herein, Ruzicka discloses a catheter having a distal end formed from a metal having thin walls. The thin metal construct is ***twisted*** at the distal end. It does not include "a coil-shaped region . . . forming a spiral having at least one turn," as required by independent claim 3. Since Ruzicka does not disclose a coil-shaped region, it certainly dose not disclose a coil-shaped region having an outer diameter that is substantially equal to an outer diameter of the remainder of the catheter. Accordingly, Ruzicka does not remedy the deficiencies of Macaluso.

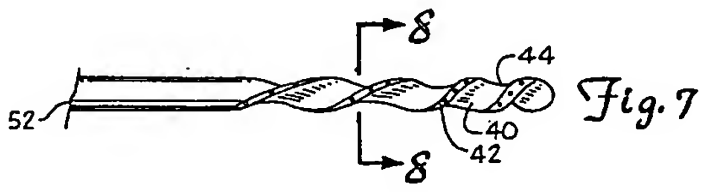


Fig. 7

Davey also fails to remedy the deficiencies of Macaluso or Ruzicka because Davey does not teach or even suggest a catheter having a coil-shaped region with a diameter that is the same as the diameter of the proximal portion of the catheter, as required by claim 3. In fact, Davey

likewise fails to teach any type of coil-shaped catheter. Davey merely discloses a catheter having a tapered distal portion. The use of such a tapered distal portion with the catheter disclosed by Macaluso would not result in a catheter having a coil-shaped region as claimed. Rather, the diameter of the coil-shaped region of Macaluso would continue to be significantly larger than the diameter of the remainder of the catheter, as shown in Figure 7, because the coil has a specific size and configuration that allows it to fit within the renal pelvis. Neither reference teaches forming the coil-shaped region such that the outer diameter is substantially equal to the outer diameter of the remainder of the catheter.

Applicants further note that even if Ruzicka or Davey did disclose a spiraled tip having a diameter that is the same as the diameter of the catheter itself, which they clearly do not, a person having ordinary skill in the art at the time of the invention would not have been motivated to modify the catheter of Macaluso to include such a spiral tip. Macaluso discloses a catheter having a helix that is adapted to fit "***tightly within the renal pelvis*** 12, as shown in FIG. 3." (Col. 3, lines 50-51, emphasis added.) Since the helix is specifically shaped and sized to fit within the renal pelvis, it would not have been obvious to modify Macaluso, in view of Ruzicka, Davey, or any other reference, to have a coil-shaped region with an outer diameter that is substantially the same as the outer diameter of the proximal portion of the catheter. Such a modification would not improve the performance of Macaluso, and in fact it may hinder proper drainage. Accordingly, there is no motivation for such a modification.

In sum, Macaluso, Ruzicka, and Davey all fail to teach or even suggest a catheter having a coil-shaped distal portion with an outer diameter that is substantially equal to an outer diameter of the proximal portion of the catheter, and therefore claim 3 represents allowable subject matter. Claims 5-18 are allowable at least because they depend from an allowable base claim.

In the pending Office Action, the Examiner further argues that the applicant has not disclosed that the specific dimensions and shapes solve any stated problem or are for any particular purpose. Applicants disagree. One significant problem with prior art hydrocephalus catheters is that they tend to become blocked or clogged, as discussed in the Background of the

Invention section of the present invention. Applicants have solved this problem by providing a coil-shaped distal portion that is effective to prevent tissue and debris from clogging fluid inlet ports formed on the internal portion of the coil-shaped region. The formation of a coil on the distal end of a catheter having a constant diameter along the length thereof would, however, necessarily result in a coil-shaped region having a diameter that is significantly larger than the diameter of the proximal portion of the catheter. The catheter would thus either have a distal portion that is too large for use as a ventricular catheter, or conversely it would have a proximal portion with a diameter that is not sufficient to allow fluid to flow therethrough. Accordingly, by reducing the diameter of the distal portion such that the diameter of the coil-shaped portion is substantially the same as the diameter of the proximal portion of the catheter, the claimed coil-shaped portion can be implanted without potentially causing damage to the patient, and it remains effective in preventing clogging of the inlet ports and draining fluid.

Independent Claim 19

New claim 19 also distinguishes over Macaluso, Ruzicka, and Davey. In particular, claim 19 requires a coil-shaped region having successive turns that are spaced apart from one another by a distance that is *adapted to prevent tissue from growing into the coil-shaped region*. None of the references teach or even suggest such a configuration.

As noted above, Macaluso discloses a catheter having a helix that is loosely wound to fit within the renal pelvis, and thus that has successive turns that are spaced apart from one another by a significant distance. This distance is clearly large enough to allow tissue to grow into the helix, and any modification of the distance between the turns on the Macaluso catheter would render the device inoperative for its intended use as the helix would no longer fit within the renal pelvis.

Ruzicka and Davey likewise fail to disclose a catheter having a coil-shaped region that is adapted to prevent tissue from growing into the coil. As noted above, neither Ruzicka nor Davey teach or even suggest any type of coil-shaped catheter. Rather, the distal end of the Ruzicka catheter is merely twisted, and the Davey catheter is merely tapered.

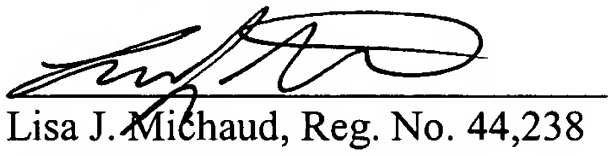
Accordingly, claim 19 distinguishes over Macaluso, Ruzicka, and Davey and represents allowable subject matter. Claim 20 is allowable at least because it depends from claim 19.

Conclusion

In view of the amendments and remarks above, Applicants submit that claims 3 and 5-20 are in condition for allowance. In the event that the above amendments and remarks are not deemed to place this case in condition for allowance, an opportunity to interview with the Examiner is requested. Applicants encourage the Examiner to telephone the undersigned upon receipt of this response to discuss any issues that may remain.

Respectfully submitted,

Date: November 1, 2004



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